REMARKS

A. Status of the Claims

Claims 182-196 were pending at the time of the Action. Applicants note that a Preliminary Amendment was filed in the case by facsimile on May 13, 2004, which was prior to the mailing date of this Office Action. To the extent that this Action reflects the non-amended claims, Applicants respectfully request reconsideration in view of the comments herein and claims filed May 13, 2004. The Listing of Claims presented above reflects the claims as amended in the Preliminary Amendment.

B. Rejection Under 35 U.S.C. §112 - Enablement

Claims 182-196 have been rejected under 35 U.S.C. §112, first paragraph, as not being enabled by the specification. In particular, it is stated that the working examples in the specification do not show that the PAGs identified are absent about two months post-partum and that there is a lack of working example showing PAG analysis using biological samples from saliva, serum, milk or urine.

In response, Applicants direct attention to the attached Declaration of Dr. Jonathan A. Green (Appendix A). This evidence demonstrates enablement of the full scope of the claims. In particular, Dr. Green describes studies carried out demonstrating that PAGs 4, 6, 7, 16, 17, 20 and 21 are indicators of pregnancy undetectable by about two-months post-partum. The studies further describe use of antibodies that immunologically bind these PAGs in maternal serum for early pregnancy detection in accordance with the claims. In the Declaration, Dr. Green outlines studies showing isolation of three monoclonal antibodies binding immunologically to the PAGs. Based on the results, Dr. Green concludes that:

> the descriptions in the patent application enable a person of ordinary skill in reproductive biology to, without more than routine experimentation, (a) obtain a sample from a bovine animal; and (b) detect at least one pregnancy associated antigen (PAG) in the sample that is present early in pregnancy and is undetectable at about two months post-partum; where detection of the PAG indicates that the animal is pregnant.
>
> (Declaration of Jonathan A. Green, ¶13)

The demonstration of enablement for these 7 PAGs, each described in the specification and falling within the claims, demonstrates enablement for the full scope of the claims. This constitutes well more than a representative number of PAGs. Applicants need only provide one method for making and using the claimed invention with a reasonable correlation to the entire scope of the claims. MPEP §2164.01(b) (citing *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA 1970)); see also See *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (quoting *Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)) ("The enablement requirement is met if the description enables any mode of making and using the invention."). Applicants have more than met this standard and therefore this aspect of the rejection is now believed moot.

With respect to different sample types, Applicants first note that the attached Declaration of Jonathan A. Green demonstrates detection of PAGs from bovine serum, as described above. This issue is therefore believed moot. With respect to remaining sample types, the ability to detect PAG in the milk of goats was described in *Theriogenology* (2001) 56:671-676. The inventors have further obtained preliminary data showing that PAG presence is not limited to serum and is found in saliva, milk and urine. Specifically, studies carried out by the inventors showed by ELISA with both polyclonal and monoclonal anti-PAG antibodies that PAG was present in the milk of four of seven pregnant cows tested (Green Declaration ¶13). In the polyclonal assay, five of the seven pregnant animals exhibited reactivity in urine, whereas the

monoclonal antibodies detected PAG in two of the seven pregnant urine samples. (Green Declaration ¶13). Although saliva samples were available for only five of the pregnant animals, all showed the presence of PAG in the polyclonal-based assay, while three of the pregnant saliva samples were positive in the monoclonal-based assay. **(Exhibit 4)**. The examples presented therefore establish enablement of the full scope of the invention by showing the presence of PAG in various sample types. In fields such as this where the art typically engages in experimentation, even complex experimentation is not necessarily undue. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). Further, Applicants need only provide one method for making and using the claimed invention with a reasonable correlation to the entire scope of the claims. MPEP §2164.01(b). Applicants here have more than fully satisfied this standard.

In view of the foregoing evidence and legal standards, it is submitted that enablement for the full scope of the claims has been established. Removal of the rejection is therefore respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects claims 182-196 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which Applicants regard as the invention. The individual rejections and Applicants' responses are set forth below.

(1) In claim 182 it is stated that the recited PAGs must include a SEQ ID NO. In response, it is noted that the current claims as amended in the Preliminary Amendment filed prior

to the mailing of the Office Action do not recite specific PAG antigens. It is therefore believed that the rejection is moot and removal thereof is thus respectfully requested.

(2) In claim 193, line 2, it is stated that "a first antibody" is indefinite because it is unclear what this antibody is for or what function is involved. Applicants respectfully traverse. The text in which the term is used in the claim recites "...binding the PAG to a first antibody preparation..." It is therefore respectfully submitted that the claim requires that the first antibody bind the PAG. The claim therefore requires this function for the PAG and the recitation of "first antibody" is thus not unclear.

In view of the foregoing, removal of the rejection is respectfully requested.

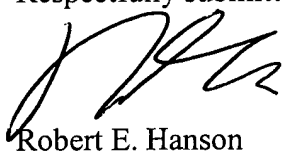
D. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and a notification to that effect is earnestly solicited. Should the Examiner have any questions regarding this response, a telephone call to the undersigned in invited.

PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136(a), Applicants petition for an extension of time of one month to and including September 20, 2004 in which to file the instant response. Pursuant to 37 C.F.R. § 1.17, a check in the amount of $110.00 is enclosed, which is the process fee for a one month extension of time. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the instant response, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Account No.: 50-1212/UVMO:003USC1.

Respectfully submitted,



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